EXHIBIT A

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE)
LITIGATION) MDL No. 1456
) Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:) Hon. Patti B. Saris
United States of America, ex rel. Ven-a-Care) Magistrate Judge Marianne B. Bowler
of the Florida Keys, Inc., v. Abbott)
Laboratories, Inc.,)
CIVIL ACTION NO. 06–CV-11337-PBS)

UNITED STATES' [PROPOSED] CORRECTED MEMORANDUM IN SUPPORT OF ITS THIRD MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS FROM ABBOTT LABORATORIES INC. AND TO REQUIRE THAT ABBOTT DEDESIGNATE NON-CONFIDENTIAL INFORMATION

The United States of America, through its undersigned counsel, respectfully files this [Proposed] Corrected Memorandum in Support of Its Third Motion to Compel the Production of Documents from Abbott Laboratories Inc. ("Abbott"), and to Require that Abbott De-Designate Non-Confidential Information.

I. STATEMENT OF FACTS

A. Background

This is a case brought by the United States against Abbott under the False Claims Act and the common law, for its alleged scheme to defraud the Medicare and Medicaid programs, which provide for the health care needs of the poor, the elderly and the disabled. Judge Saris has ordered that discovery be completed in this case by December 31, 2007; Abbott's failure to timely produce relevant documents severely jeopardizes that deadline, as set forth below.

On July 19, 2006 and November 17, 2006, respectively, the United States served its first

two sets of document requests. *See* Exhibits ("Ex.") 1 and 2. Abbott has produced very little in response. In the face of Abbott's recalcitrance, the United States has attempted every reasonable approach without success, including meet and confer sessions, telephone calls, and written communications and reminders such as emails and letters. Most recently, the United States summarized all of its outstanding requests and communications in an omnibus September 17, 2007 letter to Abbott. *See* Ex. 3, September 17, 2007 Letter from R. Brooker to J. Daly, J. Winchester, and C. Geisler ("omnibus letter"). We requested a response by October 1, 2007, in lieu of filing the present motion to compel, given the pressing discovery deadline. The United States did not receive a response from Abbott until October 12, 2007 (the letter was dated October 11). *See* Ex. 8. The United States has reviewed Abbott's late response, and incorporated it herein, before filing the instant motion.

In addition to its late productions, the United States has an even more serious concern with Abbott's document production in this case. Abbott has been improperly wielding its discretion to determine the relevance of materials. While there are numerous examples to cite, three illustrate our concern. First, only after extensive and wasteful motions practice by Abbott, including a motion to reconsider, has the United States gained access to highly relevant materials that Abbott earlier produced in the Texas AWP case but selectively removed (at extra expense to itself) from the CD-ROMS it produced in this case on the basis of relevance objections. *See* Judge Saris's Orders at Ex. 7 at 1, and 7 at 3 (Judge Saris's 08/21/07 electronic Order on Relator's April 27, 2007 Motion to Compel Abbott to Produce or Consent to Access To and Sharing of All Discovery Produced by Abbott in Other False Price Report Litigation; and 09/06/07 electronic Order denying Abbott's Emergency Motion to Stay the Effect of and Motion

to Reconsider the Court's August 21, 2007 Order).

Second, the United States learned secondhand through private plaintiffs of hundreds of thousands of Abbott emails that were relevant to the United States' case – emails that were provided to private plaintiffs in the first instance only after motions practice. See Ex. 4 at 75. It was not until August 22, 2007 that the United States received that e-mail production, and questions about the completeness of the production still remain unanswered. See Ex. 3 at 12. Third, Abbott continues to selectively limit its document production on the basis of time period. Abbott limited its production to 2001 on the basis of relevance until the Court ordered production through 2003 (Dkt. No. 4244). However, Abbott selectively produced on October 11, 2007, a highly relevant document that appears to show that Abbott put in place, on or about September 22, 2004, a written policy that says Abbott employees should not market the spread. However, it appears that Abbott is taking the position in this litigation that Abbott implemented a policy not to market the spread, well over a decade after the United States alleges Abbott was marketing the spread. See e.g., Ex. 3 at 4 (questions posed by Abbott counsel at the deposition of pharmaceutical marketing expert, Dr. Perri). If Abbott put in place a policy at some point in 2004, or at any time (including before 1991), *not* to market the spread, the United States is entitled to explore the implementation, reasons, purposes, and application of any such policy because it would be highly relevant to this litigation, regardless of time period. See e.g., Court Order for the production of documents regarding HPD drugs pertaining to how Abbott "put

¹"Abbott employees may not use or provide Customers with tools to enable reimbursement modeling which may be used to determine the margin between acquisition costs and reimbursement amounts ("spread")." Ex. 9 (ABT-DOJ 0302499), document produced via Ex. 8 at 3.

together the spread." (Dkt. No. 4244).

Abbott's withholding of relevant documents in this case is consistent with its approach to discovery in other matters. Abbott required, for example, the state of Texas to litigate Abbott's writs of mandamus in a fruitless effort to prevent the Texas court's orders on document production from having force and effect.² Although Abbott's bold tactics in Texas were entirely unsuccessful and also led to sanctions in at least one instance, it caused extraordinary delay and expense to the state of Texas and Relator Ven-A-Care, and clogged the docket of the Texas court. Thus, the United States is attempting to avoid motions practice in this case leading all the way up to the discovery deadline.

A deadline for the completion of Abbott's document production is necessary to meet the Court ordered December 30, 2007 discovery deadline in this case. (Dkt. No. 3956). Document production in a case of this magnitude, even if completed on a rolling basis, requires electronic scanning, imaging, searching and review by counsel. Obviously, this process cannot happen overnight, and must occur before meaningful document review and preparation for depositions can take place. Because of Abbott's failure to produce large categories of relevant documents, as set forth below, the United States has been unable to complete or close the depositions of former and current Abbott employees. As a corollary, Abbott's failure to produce documents seriously compromises the timely completion of the reports of experts whose work is due January 31, 2008 (Dkt. No. 3956), and depends upon Abbott's documents, data and deposition testimony. Abbott

²The Texas Court of Appeals and the Supreme Court of the State of Texas denied Abbott's petitions for writs of mandamus. Most recently, on October 5, 2007, the trial court in Texas granted the state of Texas's Motion to Compel Abbott to produce all responsive electronic data and for sanctions. *See* Ex. 5 (Texas Orders).

has provided the United States with no indication whatsoever of the volume of materials it still has to produce. To add to the delay, we expect that once this motion is fully briefed and argued, Abbott will request that the Court allow it an additional month to produce documents, as has been its practice. In short, these delays, whether by design or lack of diligence, have prejudiced the United States' ability to prepare properly its case for trial. For these reasons, the United States requests that Abbott be required to produce all responsive documents within ten days.

B. Categories of Relevant Documents

The United States asks this Court to compel Abbott to produce the following categories of highly relevant documents as fully set forth in greater detail in the United States' September 17, 2007 omnibus letter (Ex. 3), and responded to by Abbott by letter dated October 11, 2007:

(1) AWP, spread, government reimbursement, price reporting documents beyond those in the Hospital Products Division files. Abbott's production to date has generally been limited to documents that had been in the possession of its Hospital Products Division, the division that was specifically involved in the manufacturing of the drugs at issue in the case. In a September 7, 2007 Order on third party discovery (Dkt. No. 4701), Judge Saris clarified that all documents regarding marketing a spread on AWP, price reporting, price reporting to a compendia and lobbying are relevant regardless of (in some instances) drug, division, time period. The United States believes that it would not make sense that Abbott's production of documents be more limited than third parties' productions. Thus, we request that Abbott be ordered to supplement its production consistent with that Order. There are Abbott documents from outside the Hospital Products Division that are highly relevant to this case that have not been produced.

For example, the government has some Abbott documents from its criminal and civil prosecution of Abbott's Ross Products Division wherein Abbott discusses AWPs, spreads, and government reimbursement. In a July 17, 2000 power point presentation to Cardinal Health, Ross Products employee Michael Tootell discusses developments in government reimbursement noting "AWPs are determined by manufacturers." *See* Ex. 6 at 2 (ROSS 424464). Abbott contests in this case that it has any involvement in the setting of AWPs. (*See e.g.*, 06/19/07 Hearing before this Court where Abbott counsel represented that "Abbott does not set the AWP. They [the United States] keep trying to do that.

They keep trying to put that on us. We're not going to be able to give them anybody at Abbott who set AWP because we don't set AWP. That is the pricing compendia." Ex. 10 at 46:18-21). Abbott has not produced this document in this case; if the United States did not happen to have it from another investigation, it would never have been aware of this admission by Mr. Tootell that manufacturers, like Abbott, "determine AWPs."

- (2) Court Ordered Sales and Marketing Documents. On May 22, 2007, this Court ordered the production of *inter alia* "all documents that relate to the subject drugs including, general sales and (across the board) marketing information that would encompass the subject drugs." (Dkt. No. 4244). It appears that Abbott has produced a small subset of the marketing plans from 1991 to 2003, which counsel has represented to be the *only* marketing plans created and maintained by Abbott for the subject drugs for this entire time period, namely "August Plan/April Update" documents. *See* Ex. 8 at 2; Ex. 3 at 3-5; *see also* Ex. 4 at 120 (07/25/07 letter from R. Ford to J. Winchester) and Ex. 4 at 110 (08/31/07 letter from R. Brooker to J. Winchester). We request that Abbott be ordered to inform the United States whether the remainder of these documents have been destroyed, and the date and circumstances. Abbott's October 11 letter does not mention any marketing documents beyond the documents that counsel informed us about. *See* Ex. 8 at 2. In addition, we request that Abbott be required to confirm that it has produced all documents that are covered by this Order.
- (3) Court Ordered Personnel Files of ASPS Field Sales Force. At a hearing on May 16, 2007 (Ex. 11, Tr. at 56), this Court also ordered the production of these materials. See Ex. 3 at 5-6. Even though the Court did not specify a deadline, these materials should have been produced within thirty days of that hearing. Abbott has taken unfair advantage of the fact that Judge Bowler did not expressly set a deadline for the production. Abbott now promises for the first time in its letter of October 11, 2007 to complete the production of this category by October 31, 2007. See Ex. 8 at 2. If that promise is met, we will withdraw our request on this category.
- (4) Court Ordered Documents Regarding Alternate Site's Bottom 20% Customers. Abbott was required to produce these materials in accordance with this Court's rulings at the May 16, 2007 hearing on the United States' motion to compel. See Ex 11 at 68:19-23. Despite months of promises that these materials would be produced, Abbott has not completed its production. See Ex. 3 at 6-7. In its letter of October 11, 2007, Abbott refers to contracts and transaction data only, ignoring completely that the request calls for a larger production of all document relating to these customers, including but not limited to emails, correspondence or any form of communications with customers. See Ex. 8 at 3.
- (5) Home Infusion Documents. The United States' First Amended Complaint

includes numerous allegations about a home infusion business Abbott operated that directly profited off Abbott's alleged price fraud scheme. In May 2007, Abbott claimed it had documents related to this business unit that it was to produce. See Ex. 3 at 8-9. In our omnibus letter of September 17, 2007, we enumerated 18 categories of documents related to its Home Infusion unit. See Ex. 3 at 9. To date, Abbott has not produced on its promises. See Ex. 3 at 8-9. In its letter of October 11, 2007, Abbott promised yet again to produce 80 boxes of materials by October 31, 2007. See Ex. 8 at 2. However, given Abbott's prior promises, and the impending discovery deadline, we believe a court ordered deadline is necessary. Furthermore, Abbott refuses to produce category 7, the HCFA 1500 forms, and cannot confirm that its production will include all the categories of documents requested by the end of the month. See Ex. 8 at 2.

- (6) **Transactional Sales and Other Data**. Perhaps most critically, Abbott has not provided a complete and accurate set of data, which includes all of the transactions involving the subject drugs in this case. This information is critical for both establishing liability and damages. Moreover, the work of experts cannot be close to completed without accurate and complete data. Recently, Abbott has been sanctioned for providing faulty transaction data in related state court litigation after years of motions practice to obtain the same data (Ex. 5, 10/05/07 Texas Court Order), and the United States is seeking to avoid being in a similar situation. *See* Ex. 3 at 12-17.
- (7) **Acyclovir Data**. The United States added Acyclovir Sodium in its First Amended Complaint. Abbott has refused to provide documents and transaction data related to that drug because of its pending Motion to Dismiss. *See* Ex. 3 at 16-17. That is not a legitimate basis to withhold information. Discovery has always proceeded in this case with a pending motion to dismiss. We seek prompt production of this additional data.

In addition to producing documents in these categories within ten days, the United States asks the Court to order Abbott to produce all documents responsive to the requests in the United States' First and Second Requests for Production or confirm that all responsive documents have been produced. All documents produced in response to any order to compel granted by this Court should be produced in accordance with the requirements of the Protective Order, and Judge Saris's four recent rulings on confidentiality, discussed further below.

C. Meet and Confer Efforts

The United States has had many fruitless meet and confer sessions and other communications with Abbott. Attached as Ex. 4 are copies of the voluminous correspondence between Abbott and the United States regarding the United States' First and Second Requests for Production. Despite dozens of communications from the United States, Abbott has failed to meet its promised deadlines, or meaningfully produce documents in time for document review and depositions before the close of fact discovery, necessitating this motion.

II. ARGUMENT

In order to meet the discovery deadline set in this case, Abbott must produce all relevant documents expeditiously. Further, we request the Court to order Abbott make good faith redesignations of "Confidential" or "Highly Confidential" documents, and provide explanations for its designations in the future. Further discussion is below.

A. Document Production

It is well settled that parties may obtain discovery regarding any matter, not privileged, which is "relevant to the claim or defense of any party." Fed. R. Civ. P. 26(b)(1); *Matthews v. Allen*, 2006 WL 2228845 at *1 (D. Mass. 2006). "Mutual knowledge of all the relevant facts gathered by both parties is essential to proper litigation." *Atchison Casting Corp. v. Marsh, Inc.*, 216 F.R.D. 225, 227 (D. Mass. 2003) (quoting *Hickman v. Taylor*, 329 U.S. 495, 507-08 (1947); and citing *United States v. Mass. Indus. Fin. Agency*, 162 F.R.D. 410, 414 (D.Mass.1995) and *Cabana v. Forcier*, 200 F.R.D. 9, 17 (D.Mass.2001) for the proposition that relevancy must be broadly construed at the discovery stage).

It is equally well settled that the mere statement by a party that discovery is burdensome or not relevant is inadequate to voice a successful objection. The party resisting discovery must

show specifically how each interrogatory or document request is overly broad, burdensome, irrelevant, or oppressive. *Josephs v. Harris Corp.*, 677 F.2d 985, 991-92 (3d Cir.1982) (interrogatory responses); *Redland Soccer Club, Inc. v. Department of Army of U.S.*, 55 F.3d 827, 856 (3d Cir. 1995) (document requests); *McLeod, Alexander, Powel & Apffel, P.C. v. Quarles*, 894 F.2d 1482, 1485 (5th Cir. 1990) (applying the 3rd Circuit's standards in *Josephs* regarding interrogatory responses to document requests, namely requiring a party to show specifically how each document request is not relevant, overly broad, burdensome or oppressive); *see also, Lamoureux v. Genesis Pharm. Servs.*, 226 F.R.D. 154, 158 (D.Conn.2004) (interrogatory responses); *A. Farber & Partners v. Garber*, 234 F.R.D. 186, 188 (C.D. Cal. 2006) ("boilerplate relevancy objections, without setting forth any explanation or argument why the requested documents are not relevant, are improper").

The documents sought are highly relevant, as set forth in detail in our omnibus letter. *See* Ex. 3. Therefore, Abbott, the party opposing discovery in this instance, has the burden of demonstrating that the discovery is unduly burdensome or irrelevant. After more than a year, Abbott has made no such credible claims. Indeed, in many instances, it has promised to produce documents, and simply failed to make good on those promises.

B. <u>Documents Marked Confidential or Highly Confidential</u>

Judge Saris has issued in this AWP MDL proceeding four rulings related to the improper designations of confidential materials in court filings. *See* Orders at Ex. 7 at 2, 7 at 5 (¶9), 7 at 6, 7 at 7. In her Order of September 7, 2007 (Dkt. No. 4701), finding the assertion of confidentiality "frivolous," Judge Saris ruled that "[n]o further documents shall be sealed in this case unless counsel asserting confidentiality asserts the basis for the claim in a pleading subject

to the sanction of Fed. R. Civ. P. 11." On October 10, 2007 (Ex. 7 at 6), in an electronic order on Non-Party Cardinal Health's Motion to Protect Confidential Proprietary Commercial Information, allowed only in part, Judge Saris found that:

pricing information from more than 5 years ago is not sensitive commercial information. Accordingly, all average acquisition costs from 2002 to date may be redacted. All other information in Ex. B shall be publicly available. Just because Cardinal states something is confidential does not necessarily mean it can establish good cause to seal. For example, it is inconceivable that commercial information from the 1990's is sensitive business information now.

The United States believes that many of Abbott's confidentiality designations have been frivolous. Ex. 3 at 19. In fact, even as recently as October 11, 2007, *after* Judge Saris issued all four of these rulings, Abbott produced a CD-Rom of almost approximately 2,000 pages. *See* Ex. 8. From a random sampling of this production, it appears that Abbott has labeled every single page in the production as "Highly Confidential." Some sample pages from this production are attached to this motion. The first document is referred to as a policy document pertaining to federal health care reimbursement from Abbott's Office of Ethics and Compliance, and was issued on September 22, 2004. *See e.g.*, Ex. 9 (ABT-DOJ 0302496-2502). The United States does not believe that this policy document, which Abbott agreed to publicly filing a couple days after producing it, meets the standards set forth by Judge Saris in her October 10 electronic Order. *See* Ex. 7 at 6. The second item is a single page (50) from Abbott's 1990-1994 Long Range Plan. *See* Ex. 9 (ABT-DOJ

³The United States received these documents from Abbott on Friday, October 12. *See* Ex. 8. On Monday, October 15, we asked Abbott whether we could publicly file these several pages. *See* Ex. 4 at 145-151. Abbott stated that it did not have time enough on Monday to investigate whether it would object to filing 7 pages of the 1990-1994 plan under seal. It did not object to the United States publicly filing a single page (page 50). <u>Id.</u> In order not to further delay the filing of this motion, the United States chose to file only the single page to which Abbott did not

0302462). This document also would not appear to comply with Judge Saris's recent Order.

Abbott's improper designations create inefficiencies and compromise the United States' ability to prepare effectively this case for trial. While the Court's recent Orders have been in the context of motions for leave to file under seal documents, the United States' believes the Court's concern would extend to Abbott's wholesale designation of documents as confidential in discovery, which leads to sealing motions like the ones recently denied.

Based on Judge Saris's rulings, the United States believes it is appropriate that Abbott be required to review the entirety of its document production in this case, almost all of which it has designated as "Confidential" or "Highly Confidential," and make good faith proper designations in accordance with the Protective Order in this case (Dkt. No. 3752-2). As a result, the United States requests that the Court order Abbott within twenty (20) days to de-designate all documents and transcripts it previously marked as "Confidential" or "Highly Confidential," except those that truly meet the good faith requirements set forth in the Protective Order. Moreover, we ask the Court to order Abbott to comply with Judge Saris's October 10, 2007 electronic Order (Ex. 7 at 6), and de-designate "all pricing information from more than 5 years ago," and "all commercial information from the 1990s." Further, the United States requests that Abbott provide the good faith basis of any confidentiality assertions it makes on documents produced during the remainder of discovery. (See Ex. 7 at 2 and Ex. 7 at 5, Orders of Judge Saris, 09/06/07 and 09/07/07, ruling that parties must provide a good faith basis for asserting any confidentiality designation subject to

object. Abbott's after-the-fact investigation of the confidentiality of a document it marked and produced only a few days ago with a stamp of "Highly Confidential" illustrates the need for the requested relief.

⁴This would include, but not be limited to, the average manufacturer data ("AMP") data produced by Abbott in this case. *See* Ex. 4 at 94.

Fed. R. Civ. P. 11).

III. CONCLUSION

For the reasons stated above, the United States respectfully requests that the Court overrule Abbott's objections and order it to produce the several categories of documents identified above within ten (10) days. The United States also respectfully requests that this Court order Abbott to produce within ten (10) days all documents responsive to the requests in the United States' First and Second Requests for Production, or confirm that all responsive documents have been produced. Further, we request that this Court order Abbott to comply with Judge Saris's September 7, 2007 Order on third party discovery (Dkt. No. 4701), and produce *inter alia* "all documents which refer or relate to Abbott's marketing a spread on a drug involving AWP no matter what drug or what year." Finally, we request that the Court order Abbott within twenty (20) days to de-designate all improperly designated materials, including but not limited to, the categories set forth in Judge Saris's October 10, 2007 order (Ex. 7 at 6), and provide the good faith bases for future designations of "Confidential" or "Highly Confidential" documents.

Respectfully submitted,

For the United States of America,

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Dated: October 17, 2007

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CERTIFICATION

The undersigned counsel certifies pursuant to LR 7.1(a)(2) that she conferred with counsel for the Defendant Abbott Laboratories, Inc. on the issues raised in this motion and have not been able to reach agreement.

/s/ Renée Brooker Renée Brooker

Dated: October 17, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above United States' [Proposed] Corrected Memorandum in Support of Its Third Motion to Compel the Production of Documents From Abbott Laboratories Inc. and To Require That Abbott De-Designate Non-Confidential Information to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Renée Brooker Renée Brooker

Dated: October 17, 2007